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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff,

- against -

XAVIER BECERRA, in his official capacity as Attorney General of the State of California,

Defendant.

COMPLAINT

Plaintiff Association for Accessible Medicines ("AAM") brings this complaint for declaratory and injunctive relief against Xavier Becerra, in his official capacity as Attorney General for the State of California (the "Attorney General"). AAM brings this complaint based on personal knowledge as to all AAM facts, and on information and belief as to all other matters.

PRELIMINARY STATEMENT

1. Generic and biosimilar medicines enhance Americans' access to lifesaving medications. These equally safe and effective alternatives to brand-name drugs help drive down the often sky-high prices of prescription medicines, and thus ensure better healthcare for everyone.

2. But they cannot enter the market while a patent monopoly remains in place. Under the patent system, generic and biosimilar medicines typically must wait until after the patents protecting the relevant brand-name drugs either have expired or have been invalidated in court.

3. Given that feature of the American prescription-drug market, often the only way to speed lower-priced, but equally safe and effective, generic and biosimilar medicines onto the market is through settlement agreements resolving patent infringement litigation.

4. Patent settlements help shave years off brand-name drug companies' monopolies, and they save everyday Americans billions of dollars each year.

5. Many generic and biosimilar medicines that have come to market prior to patent expiry in recent years would not have done so were it not for patent settlements. That is because there is often no viable alternate route to early entry of generic and biosimilar medicines or to bringing down the cost of brand-name drugs more generally. The cost of pharmaceutical patent litigation is extremely expensive and time-consuming, with the average case costing each side many millions of dollars in fees and taking many years from complaint to resolution.

6. Even when a brand-name drug is protected by just a single patent, those dollars and years add up. In fact, however, it is increasingly rare for a high-value brand-name drug to be protected by only one patent. Brand-name prescription medicines are increasingly backed up by large patent portfolios that include scores of follow-on patents.

7. The follow-on portfolio for some brand-name drugs consists of more than 100 separate patents. Challenging all of those patents would take tens (if not hundreds) of millions of dollars, and would take many years (if not more than a decade). In the interim, the brand-name drug would be the only game in town—free to charge patients on whose lives it depends monopolist prices. After all, even a single patent can keep all generic alternatives off the market.

8. Nor is success guaranteed when a generic or biosimilar manufacturer challenges the validity of a patent protecting a higher-priced brand-name drug. To the contrary, as a 2010 study found, generic manufacturers prevailed in less than half of the patent cases they litigated to judgment. RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (Jan. 15, 2010),

https://amlawdaily.typepad.com/pharmareport.pdf; *see also* Br. for the Generic Pharm. Ass'n as *Amicus Curiae* Supporting Respondents ("*Actavis* Br. for Generic Pharm."), *FTC v. Actavis, Inc.*, No. 12-416, 2013 WL 769341, at *16-*17 (U.S. Feb. 28, 2013) (patent claims are upheld roughly half the time even in cases challenging secondary or follow-on patents).

9. Frequently, then, the only viable way a generic or biosimilar manufacturer can bring its lower-priced but equally safe alternatives onto the market prior to the expiration of all applicable brand-name drug patents is through settlement agreements resolving patent litigation.

10. Unfortunately, Assembly Bill No. 824 ("AB 824" or "the Act") (Exhibit A), threatens to render such settlements relics of the past. Indeed, it already has caused generic and brand-name drug manufacturers to decline and/or pull pro-competitive settlement offers that would have been accepted but for AB 824—thereby causing AAM's members economic injury (because now they are left litigating infringement suits at considerable expense, and with uncertain prospects of success, having lost the value they would have received under the settlements) and harming patients too by doing away with the price savings patent settlements help bring about.

11. AB 824 has had these effects, and will continue to have these effects, because it fundamentally changes the landscape. Unlike under the test the Supreme Court laid out in *FTC v. Actavis*, AB 824 renders presumptively unlawful a vast array of settlement agreements that resolve pharmaceutical patent infringement suits and makes it nearly impossible for a settling company to run the gauntlet and overcome all of its interlocking presumptions. And unlike under extant federal and state laws, AB 824 makes each ***person***—not just each company that signs an agreement deemed to violate its terms—who assists in a settlement deemed to violate the statute liable for penalties of at least ***twenty million dollars***, even if she received no value as a result.

12. AB 824 will have perverse and far-reaching consequences not just for generic and biosimilar manufacturers, but for patients both in and out of California. By presuming that run-of-the-

mill patent settlements are unlawful and imposing massive penalties on individuals who merely assist in a settlement later deemed to violate its terms, AB 824 will create—and, indeed, ***has already created***—significant barriers to entry for generic and biosimilar medicines.

13. The inevitable result of allowing AB 824 to be enforced will be fewer low-priced generic and biosimilar alternatives entering the market before patent expiry, resulting in ***less*** competition and ***higher*** prescription drug prices for patients nationwide—exactly the opposite of what Congress sought to achieve in the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or "Hatch-Waxman"), Pub. L. No. 98-417, 98 Stat. 1585 (codified in various sections of titles 21, 35 & 42 U.S.C.), and the Biologics Price Competition and Innovation Act ("BPCIA"), Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 119.

14. Nor does such sweeping state-level intervention serve a purpose. As the Chairman of the Federal Trade Commission ("FTC") recently emphasized, "despite a considerable increase in the total number of final Hatch-Waxman patent settlements in FY 2016," "'the Supreme Court's Actavis decision has ***significantly reduced*** the kinds of reverse payment agreements that are most likely to impede generic entry and harm consumers.'" FTC, *Press Release: FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors* (May 23, 2019) ("FTC Press Release") (emphasis added), http://bit.ly/2I1Rwof. In other words, the federal system is working as intended, protecting the rights of brand-name manufacturers to reward their research and development, but also encouraging the timely development and fostering the timely market entry of more affordable generic and biosimilar medicines. AB 824 is therefore a solution in search of a problem that, even in the eyes of the FTC, effectively no longer exists.

15. AB 824 is also unconstitutional. AB 824 regulates settlement agreements resolving pharmaceutical patent infringement suits between brand-name drug companies and manufacturers of competing generic and biosimilar medicines. It imposes crippling financial penalties for violating its

terms. And, unlike other recent California statutes, it is not limited to transactions completed in California or even connected to California. AB 824 is thus a textbook violation of the dormant Commerce Clause, which "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (citation omitted).

16. AB 824 also conflicts with federal patent laws and disrupts the careful balance Congress established in the Hatch-Waxman Act and the BPCIA. Whereas the Patent Act expressly confers the right to grant exclusive licenses and mandates that all patents must be presumed valid, AB 824 deems all exclusive licenses (not just so-called "no-authorized-generic" clauses) presumptively unlawful and anticompetitive, and it further requires courts ***not*** to presume that a patent is valid, in direct conflict with federal patent law. The conflicts with federal law do not end there. AB 824 upsets the careful balance Congress struck and the Supreme Court recognized in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). Whereas *Actavis* rejected a presumption that patent settlements are anticompetitive whenever they contain "reverse payments" and do not allow immediate generic entry, *id.* at 158-59, AB 824 adopts the very presumption *Actavis* rejected.

17. For these reasons, and as further explained below, AAM seeks an injunction against the implementation and enforcement of the Act, a declaration that the Act is unconstitutional and invalid, and any other relief this Court deems appropriate.

THE PARTIES

18. AAM is a nonprofit, voluntary association representing the leading manufacturers and distributors of generic and biosimilar medicines, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. AAM's core mission is to improve the lives of patients by advancing timely access to safe and affordable FDA-approved generic and biosimilar medications.

19. AAM's members provide Americans with generic and biosimilar medicines that are just as safe and effective as their brand-name counterparts, but substantially less expensive. In 2018, generic medicines like those produced by AAM's members saved Americans more than $5.6 billion ***every single week of the year***. AAM, *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 4 (2019), https://bit.ly/2ojfghJ ("2019 Report").

20. Nearly every AAM member-manufacturer has recently settled one or more patent-infringement suits initiated by a brand-name drug company in response to the AAM member's filing of an abbreviated new drug application ("ANDA"). Many AAM members are also currently engaged in at least one patent infringement suit initiated by a brand-name manufacturer in response to the member's filing of a Paragraph IV ANDA.

21. In many of those cases, AB 824 has altered both the course and the ultimate result of settlement negotiations. It has directly compelled AAM members to reject settlement offers and instead continue to spend money litigating cases they otherwise would have settled but for the risk of extraordinary corporate and personal penalties under AB 824. If AB 824 is enjoined, AAM members will once again be able to enter such settlements and realize the economic benefits gained from avoiding litigation costs and uncertainty.

22. AB 824 has also driven some AAM members to withdraw Paragraph IV ANDAs it had previously filed, rather than either continuing to litigate the infringement case or settling and opening itself up to a potential enforcement action under the statute.

23. Defendant Xavier Becerra is the Attorney General of California and is responsible for enforcement and administration of AB 824. At all relevant times, the Attorney General, as well as those subject to his supervision, direction, and/or control, will be acting under color of state law. Attorney General Becerra is a resident of California. He is sued only in his official capacity.

BACKGROUND

Congress Has Created Finely Balanced Processes to Incentivize Both Medical Innovation and Competition Through the Patent and FDA Regulatory Systems

24. The costs of bringing new lifesaving medicines to market are staggering. To obtain approval from the U.S. Food and Drug Administration ("FDA"), novel medicines must go through a period of rigorous testing and disclosure, which typically takes several years and costs several billion dollars. Matthew Herper, *The Cost of Creating A New Drug Now $5 Billion, Pushing Big Pharma To Change*, FORBES (Aug. 11, 2013), https://bit.ly/3g6nboi.

25. In light of the overwhelming expense of developing new medicines, pharmaceutical innovations would be few and far between if everyone could market and profit off every new invention immediately. That is where the patent system comes in. A patent allows its owner "to exclude others from profiting by the patented invention" for a period of time. *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); *see* 35 U.S.C. §§ 154(a), 271(a), 365(c).

26. Throughout much of the twentieth century, federal law required all pharmaceutical drug products—even those that were similar in every way relevant to efficacy and safety to an already-approved brand-name drug—to undergo independent and rigorous clinical testing before they could go to market. *See, e.g.*, Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 52 (2003). This regime left patent holders with an unintended windfall that hurt Americans. Given the significant costs of performing the required tests, generic manufacturers had little incentive to duplicate previously approved pharmaceutical products. *See* H.R. Rep. No. 98-857(II) at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688. Hundreds of brand-name drugs had no off-patent or generic equivalent, which left patients with little choice but to pay high prices for basic medications long after the relevant patents had expired.

27. That changed in 1984, when Congress enacted the Hatch-Waxman Act.

28. Hatch-Waxman was intended "to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting); *see also* H.R. Rep. No. 98-857(I) (1984) at 14-15.

29. "To incentivize innovation" (and therefore further the first of those policy objectives), "Hatch-Waxman grants brand manufacturers opportunities to extend their exclusivity period beyond the standard 20-year patent term: it allows a brand-name manufacturer to seek a patent extension of up to five years to compensate for time that lapsed during the FDA regulatory process, 35 U.S.C. § 156, and an additional six-month period of 'pediatric exclusivity' if the manufacturer conducts certain pediatric studies, 21 U.S.C. § 355a." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 644 (2d Cir. 2015).

30. To "promot[e] competition from generic substitute drugs" (and therefore further the second of those policy objectives), Hatch-Waxman draws sharp distinctions between brand-name drugs and their generic equivalents. *Id.* The testing requirements for a new drug application ("NDA") for patented drugs remain rigorous. *See, e.g.*, 21 U.S.C. § 355(b)(1). But generics may file a much-less-extensive and much-less-expensive ANDA that "piggy-back[s] on the brand's NDA." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-05 (2012).

31. "[T]he typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id.* at 405; *see* 21 U.S.C. § 355(j)(2)(A)(ii)-(vii), (j)(8)(B) (generic drug is bioequivalent to a brand drug if "the rate and extent of absorption" of the active ingredient is the same as with the brand drug). "In this way the generic manufacturer can obtain approval while avoiding the 'costly and time-consuming studies' needed to obtain approval 'for a pioneer drug.'" *Actavis*, 570 U.S. at 142 (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)).

32. This streamlined process for approving generics' market entry has been remarkably successful in terms of controlling healthcare costs for everyday Americans. Generic medicines now account for 90% of all prescriptions dispensed in the United States, but only 22% of the money spent on prescription drugs. 2019 Report at 4. Indeed, generic medicines saved Americans ***$2 trillion*** over the past decade, including $293 billion in 2018 alone. *Id.* Timely availability of generic drugs is thus critical to ensuring that patients have access to affordable medicine, and that the American healthcare system works for the benefit of all Americans.

33. In addition to "'speed[ing] the introduction of low-cost generic drugs to market,'" *Actavis*, 570 U.S. at 142 (quoting *Caraco*, 566 U.S. at 405), Hatch-Waxman "sets forth special procedures for identifying, and resolving, related patent disputes," *id.* at 143. As relevant here, Hatch-Waxman "requires the pioneer brand-name manufacturer to list in its New Drug Application the 'number and the expiration date' of any relevant patent," and "requires the generic manufacturer in its [ANDA] to 'assure the FDA' that the generic 'will not infringe' the brand-name's patents." *Id.* (citation omitted); *see* 21 U.S.C. § 355(b)(1). A generic manufacturer can provide this "assurance" by "certify[ing]" under Paragraph IV "that any listed, relevant patent 'is invalid or will not be infringed by the manufacture, use, or sale' of the drug described in the [ANDA]." *Actavis*, 570 U.S. at 143 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

34. Filing an ANDA with a Paragraph IV certification "automatically counts as patent infringement," *id.* (citing 35 U.S.C. § 271(e)(2)(A) (2006 ed., Supp. V)), and a generic applicant must notify the brand-name company if its ANDA contains a Paragraph IV certification, 21 U.S.C. § 355(j)(2)(B). "Filing a paragraph IV certification" thus usually "means provoking litigation," *Caraco*, 566 U.S. at 407, but with the patent holder as the plaintiff and the would-be generic seller as the defendant. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro I*"), 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) (Hatch-Waxman "alter[ed] the litigation risks of patent lawsuits," putting the Hatch-Waxman

defendant in the shoes traditionally worn by a plaintiff, given its ability to effectively initiate the lawsuit by filing a Paragraph IV ANDA).

35. "If the brand-name patentee brings an infringement suit within 45 days" of the filing of a Paragraph IV certification, *Actavis*, 570 U.S. at 143, "FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed," which usually takes at least that long (if not longer), *Caraco*, 566 U.S. at 407. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Thus, "the mere filing" of an ANDA with a Paragraph IV certification "can provide additional years of a generic-free market, regardless of the merits of the lawsuit." Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J. LEGIS. 21, 26-27 (2002).

36. Congress's overriding purpose in Hatch-Waxman, however, was "to get generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (citation omitted). To that end, Congress made the first filer of a substantially complete paragraph IV ANDA eligible for a 180-day exclusivity period, during which no subsequent paragraph IV ANDA applicant may be approved. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (j)(5)(B)(iv). That provision, which expressly authorizes exclusivity for a limited period for the first generic filer, reflects a core assumption of the Hatch-Waxman Act—namely, that generic manufacturers often need the incentive of time-limited exclusivity in order to invest the time and money required to litigate a patent challenge. Put another way, the federal regulatory apparatus designed to speed generics onto the market is premised on the insight that a short-term impediment to intergeneric competition will have greater procompetitive benefits in the long run. *See Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010).

Federal Law Likewise Ensures Timely Access to Lower-Cost Biosimilars

37. In addition to the Hatch-Waxman Act, which helps speed lower-priced generic medicines onto the market, Congress enacted the BPCIA, which regulates "biologics"—large-molecule medicines derived from living organisms—and creates a similar expedited pathway to FDA approval for more affordable "biosimilar" alternatives.

38. Enacted as part of the Affordable Care Act, the BPCIA was intended to strike a balance between encouraging price competition within this rapidly growing category of expensive pharmaceuticals and incentivizing the development of new medicines.

39. To that end, the BPCIA regulates two types of biologics—brand-name reference products and follow-on biologics called biosimilars. The BPCIA guarantees brand-name companies a 12-year period of exclusivity for new biologics. 42 U.S.C. § 262(k)(7)(A). But, much like Hatch-Waxman, the BPCIA also establishes an abbreviated pathway for the regulatory approval of medicines that are "highly similar" to a reference product. *Id.* § 262(i)(2).

40. That abbreviated pathway is particularly critical to patients, and for a simple reason—biologics are incredibly expensive, even more so than typical brand-name drugs. "Fewer than 2% of all prescriptions are biologics, yet they account for 36% of total drug spending, comprising $125.5 billion in 2018, a 9.5% increase over 2017." 2019 Report at 16; *see also* Comment of the Staff of the FTC to FDA at 3 (Oct. 27, 2015) (biologic drugs on average cost 22 times what traditional chemical or small-molecule medications cost).

41. To obtain FDA approval via the abbreviated pathway under the BPCIA, a biosimilar applicant must submit to the FDA an abbreviated Biologics License Application ("aBLA"), which, like an ANDA, relies in part on the reference product's already-FDA-approved license. 42 U.S.C. § 262(k). And like the Paragraph IV process, the BPCIA not only helps to speed biosimilar medicines to market, but also facilitates the resolution of patent disputes between biosimilar applicants and reference product

sponsors by creating procedures that lead to early litigation (and thus resolution or settlement) of infringement claims. *See id.* § 262(*l*).

42. In sum, Congress has created a system of federal statutes that balances two conflicting but fundamental federal interests: (1) protecting the patent rights of brand-name drug manufacturers to reward and incentivize research and development; and (2) encouraging the timely development and market entry of more affordable generic and biosimilar medicines.

Patent Litigation Is Extraordinarily Expensive, Risky, and Ripe for Settlement

43. "[P]atent litigation is particularly complex, and particularly costly." *Actavis*, 570 U.S. at 170 (Roberts, C.J., dissenting); *see also, e.g.*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) ("Patent litigation breeds a litany of direct and indirect costs"); *DeLaventura v. Columbia Acorn Tr.*, 417 F. Supp. 2d 147, 153 n.7 (D. Mass. 2006) ("[P]atent litigation is the slowest and most expensive litigation in the United States.").

44. And there is no such thing as a sure thing when it comes to a lawsuit for patent infringement. Patent suits involve a "jungle of technology," with "conflicting expert testimony, technical evidence, and technical arguments." Morgan Chu & Joseph M. Lipner, *Adopting A Case Theme*, in PATENT LITIGATION STRATEGIES HANDBOOK 41 (Grossman & Hoffman, eds. 2000). So "it is [always] a gamble to place a technology case in the hands of a lay judge or jury," and "there are risks involved even in that rare case with great prospects." *Cipro I*, 261 F. Supp. 2d at 208.

45. Both of those factors (high cost and uncertainty) are especially apparent in Paragraph IV litigation. The cost of Paragraph IV litigation often exceeds $10 million, three times the average patent case. *Actavis*, 570 U.S. at 170 (Roberts, C.J., dissenting). Biosimilar patent suits are even more expensive. And "[o]utcomes of drug patent infringement suits are notoriously unpredictable and error prone." Chika Seidel, Comment, S*ettlement Should Be the End of the Story: A Proposed Procedure to Settle Hatch-*

Waxman Paragraph IV Litigations Modeled After Rule 23 Class Action Settlement Procedure, 46 SETON HALL L. REV. 697, 705 (2016).

46. Moreover, the risks of patent litigation are enormous, especially for generic and biosimilar manufacturers. If an ANDA filer loses a Paragraph IV suit—which, despite the increasing number of follow-on patents, happens more often than not when cases are litigated to the judgment, *see Actavis* Br. for Generic Pharm. at 16 (citing 2010 study showing that generic manufacturers prevailed in only 82 of 171 patent infringement cases litigated to judgment in the prior decade)—its generic product cannot enter the market until after patent expiry, regardless of future events. *See* 35 U.S.C. § 271(e)(4)(A). And even when a generic or biosimilar manufacturer ***wins*** an infringement suit in district court, it can still face crippling financial liability if it launches the product only to have the Federal Circuit subsequently reverse. *See, e.g.*, Peter Loftus, *Teva Faces Possible Damages From Selling Generic Protonix*, WALL ST. J. ONLINE (Feb. 13, 2013) (noting that Apotex was found liable for $442 million in damages despite its product having been on the market for a mere 23 days), https://on.wsj.com/2lTMByh; *see also* RBC Capital Markets, *Pharmaceuticals: Analyzing Litigation Success Rates* at 7 (Jan. 15, 2010) (finding that the Federal Circuit reverses or vacates, at least in part, nearly half of the patent-infringement appeals it hears).

47. Furthermore, generic and biosimilar manufacturers typically operate on thin margins. Yet those margins would quickly turn from black to red if a manufacturer had to litigate every patent in the relevant portfolio whenever it filed an ANDA. Nor would generic and biosimilar manufacturers be able to continue financing those new applications if they came with the prospect of $10 million litigation (or more). The settlement off-ramp, in other words, is a key component in the economic calculus that Hatch-Waxman and the BPCIA created.

48. Unsurprisingly, then, the rate of settlement in patent suits generally—and in Paragraph IV and aBLA suits in particular—has traditionally outpaced the rate of settlement in the rest of civil litigation.

***The Federal Government Regulates Pharmaceutical Patent Settlements under the Antitrust Framework the Supreme Court Established in* FTC v. Actavis, Inc.**

49. The facts that gave rise to the Supreme Court's decision in *Actavis* began when a brand-name manufacturer (Solvay) filed an NDA for a new pharmaceutical product called AndroGel, which the FDA approved. *Actavis*, 570 U.S. at 144. A few years later, a generic manufacturer (Actavis) "filed an [ANDA] for a generic drug modeled after AndroGel … certified under paragraph IV." *Id.* Another generic (Paddock) did the same shortly thereafter. *Id.* at 144-45. Solvay responded by "initiat[ing] paragraph IV patent litigation against [both]." *Id.* at 145.

50. Faced with high litigation costs and uncertain prospects, the parties settled. "Under the terms of the settlement," Solvay authorized Actavis, the first ANDA filer (who therefore stood to enjoy a 180-day period of generic exclusivity), to bring its generic to market "65 months before Solvay's patent expired." *Id.* Actavis and Paddock also agreed "to promote AndroGel." *Id.* In return for those promises and "for other services the generics promised to perform," "Solvay agreed to pay millions of dollars to each generic." *Id.*; *see* Seidel, *supra*, at 699 ("pharmaceutical settlements" often "include a complex mix of side deals as well as non-monetary considerations," *e.g.*, licenses, co-development agreements, and manufacturing, supply, and distribution agreements).

51. Upon settlement, the parties reported the terms of the settlement to the Federal Trade Commission ("FTC") and the Antitrust Division of the Department of Justice, as required by Hatch-Waxman. *Actavis*, 570 U.S. at 152. After reviewing the agreement, the FTC filed suit against the settling parties, alleging that they violated federal antitrust law (specifically section 5 of the FTC Act) "by unlawfully agreeing 'to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years.'" *Id.* at 145. *See generally FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986) (Section 5 of FTC Act "encompass[es] … practices that violate the Sherman Act and the other antitrust laws."); 15 U.S.C. § 45(a)(1) (Section 5 of FTC Act) ("Unfair methods of competition in or affecting commerce, and unfair

or deceptive acts or practices in or affecting commerce, are hereby declared unlawful."). The district court dismissed the FTC's complaint, and the Eleventh Circuit affirmed. *Actavis*, 570 U.S. at 146.

52. At the Supreme Court, the FTC "urge[d the Court] to hold that reverse payment settlement agreements"—*i.e.*, settlements in which the patentee agrees to provide anything of value to the alleged infringer (*e.g.*, the ANDA filer)—"are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason.'" *Id.* at 158-59. The Supreme Court "decline[d] to do so." *Id.* at 159. As it explained, settlements with terms permitting a generic to enter the market before the expiration of the patent will often "bring about competition … to the consumer's benefit." *Id.* at 154.

53. So although the Court held that patent settlements do not receive ***absolute*** antitrust immunity whenever they allow the generic to enter a patentee's market prior to patent expiry, *see id.* at 153-58, the Court made clear that all patent settlements are not inherently suspect.

54. Under *Actavis*, only those settlements that contain "***large and unjustified***" reverse payments trigger any antitrust scrutiny at all. *Id.* at 158 (emphasis added). As the Court explained, such "unexplained large reverse payment[s]" will "normally suggest that the patentee has serious doubts about the patent's survival," and only "[a] *valid* patent excludes all except its owner from the use of the protected process or product." *Id.* at 147, 157-58 (emphasis in original).

55. The Court underscored that its holding "does not prevent litigating parties from settling their lawsuit," including "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration." *Id.* at 158. To that end, the Court offered several examples of payments that should escape antitrust scrutiny, including: (1) payments that are "no more than rough approximation" of avoided litigation expenses; (2) payments that "reflect compensation for other services that the generic has promised to perform--such as distributing the patented item or helping to develop a market for that item";

(3) payments that reflect "traditional settlement considerations"; and (4) payments that offer "any other convincing justification." *Id.* at 156, 159.

56. The Court also explained that "the likelihood [that] a reverse payment" will ***actually*** "bring[] about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification," and "[t]he existence and degree of any anticompetitive consequence may also vary as among industries." *Id.* at 159.

57. Finally, *Actavis* held that even in a case involving a patent settlement that includes a "large and unexplained" payment from the patentee to the ANDA filer, the challenger "***must prove its case as in other rule-of-reason cases***," and only those patent settlements that ***actually*** carry "significant anticompetitive effects" will violate that standard. *Id.* at 157, 159 (emphasis added); *see Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018) ("The rule of reason requires courts to conduct a fact-specific assessment of 'market power and market structure … to assess the [restraint]'s ***actual effect***' on competition." (emphasis added; ellipsis and alteration in original) (quoting *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984))); Marc G. Schildkraut, Actavis *and the Burden of Proof: Antitrust Revolution, A Muddle, or Both*, 33-SPG Antitrust 56, 56-57 (2019) (Under the rule of reason, "detailed examination" of alleged anticompetitive effects "is always necessary"; plaintiffs bear the burden to "prove that the challenged agreement had an actual anticompetitive effect.").

58. Since *Actavis*, the number of patent settlements per year has ***increased***, while the number of potentially anticompetitive agreements ***declined***, according to the FTC's own recent count, ***to only one***. *See* FTC Press Release. The federal system is therefore working: Companies have reacted to *Actavis* by establishing a place of equilibrium where procompetitive settlements can and still do happen, but anticompetitive settlements typically do not.

AB 824 Upsets* Actavis*'s Delicate Balance and is Inconsistent with the Federal Standards for Determining Whether Patent Settlements Are Permissible

59. In direct contrast to *Actavis*—and notwithstanding the fact that the Supreme Court's 2013 decision "has significantly reduced the kinds of reverse payment agreements that are most likely to impede generic entry and harm consumers," *id.*—AB 824 renders presumptively unlawful many (if not most) agreements that resolve or settle a pharmaceutical patent infringement claim.

60. Under AB 824, "an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, shall be presumed to have anticompetitive effects and shall be a violation of this section if":

> A nonreference drug filer receives ***anything of value*** from [the] company asserting patent infringement, including, but not limited to, an exclusive license …
>
> [and] [t]he nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of [its] product ***for any period of time***.

Ex. A § 134002(a)(1) (emphases added); *see also* Ex. A § 134000(d) (defining "agreement resolving or settling a patent infringement claim" as "any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim"); Ex. A § 134000(g) (defining "[n]onreference drug filer" to mean a generic or biosimilar manufacturer).

61. The statute defines "anything of value" expansively. While it carves out certain narrow categories of consideration, *see* Ex. A § 134002(a)(2), the statute makes clear that "value" includes, "but [is] not limited to, an exclusive license or a promise that the brand company will not launch an authorized generic version of its brand drug," Ex. A § 134002(a)(1)(A).

62. To rebut the presumption of illegality set forth in § 134002(a)(1), a settling party must prove by a preponderance of the evidence that "[t]he value received by the nonreference drug filer" as part of the agreement "is a fair and reasonable compensation ***solely for other goods or services*** that the nonreference drug filer has promised to provide," or that "[t]he agreement has directly generated

procompetitive benefits ***and*** the procompetitive benefits of the agreement outweigh [its] anticompetitive effects." Ex. A § 134002(a)(3) (emphases added).

63. Furthermore, the statute specifically instructs that, "[i]n determining whether" that burden has been met, a finder of fact "shall not presume," *inter alia*, "[t]hat entry into the marketplace could not have occurred until the expiration of the relevant patent exclusivity" or "[t]hat any patent is enforceable and infringed by the nonreference drug filer in the absence of a final adjudication binding on the filer of those issues." Ex. A § 134002(b).

64. AB 824 contains no language limiting its application to settlement agreements between California entities. Nor does it contain language limiting its application to agreements negotiated, signed, and/or entered in California court. That is because the Attorney General believes—contrary to basis constitutional principles and binding Supreme Court and Ninth Circuit precedent—that he has the authority to enforce California law against commercial transactions or agreements that are completed wholly outside of California, whenever those transactions or agreements have downstream effects in the state. *But see Healy*, 491 U.S. at 335-36 (the Commerce Clause "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, ***whether or not the commerce has effects within the State***" (emphasis added) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality op.))).

65. AB 824 also imposes extremely severe penalties. "Each person that violates or assists in the violation of this section" and "received any value due to that violation" "shall forfeit and pay to the State of California a civil penalty" of "up to three times the value received by the party that is reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater." Ex. A § 134002(e)(1)(A). And "[e]ach person" who "***assists*** in [a] violation of this section … shall forfeit and pay to the State of California a civil penalty" of no less than "twenty million dollars ($20,000,000)," and "up to three times the value given to other parties to the agreement reasonably attributable to the

violation of this section," ***even if she "has not received any value"*** from the settlement or his or her assistance. *Id*. (emphasis added).

66. Governor Newsom signed AB 824 into law on October 7, 2019.

67. AB 824 took effect by operation of law on January 1, 2020.

68. At oral argument at the Ninth Circuit in the prior round of this litigation, counsel for the Attorney General confirmed that the Attorney General intends to enforce AB 824 against settlements entered into out of state. *See* Ex. B at 22:10–23:24 (Q: "I'm asking you whether or not the Attorney General can tell us whether or not he intends to enforce this law with respect to agreements made outside the borders of California." A: "Yes, … we plan to[.]").

JURISDICTION

69. AAM's causes of action arise under 42 U.S.C. § 1983 and the United States Constitution. The Court has jurisdiction under 28 U.S.C. § 1331.

70. Venue is appropriate in this district pursuant to 28 U.S.C. § 1391(b).

71. AAM is authorized by its Board of Directors to sue on its members' behalf.

72. AAM serves the interests of its members, which are impaired by the threat of excessive fines under AB 824 not only to members, but to their employees and agents as well.

73. AB 824 has already caused AAM's members direct economic injury.

74. At least one AAM member recently withdrew previously-filed Paragraph IV certifications specifically because of the breadth and scope of AB 824. This member made the decision to withdraw—and forego the potential revenues it stood to earn from the product—rather than be forced either to settle the ensuing patent litigations on unfavorable terms (given the massive penalties AB 824 authorizes) or spend large sums of money litigating all of the cases to judgment.

75. AB 824 has also stymied settlement efforts in numerous pending patent cases. Multiple AAM members are currently defendants in patent litigations outside of California. Their respective

experiences are similar: Before AB 824 went into effect, the parties to the litigation negotiated a tentative agreement under which the defendant would have received something of value as that term is defined in AB 824—*e.g.*, an exclusive license, an accelerator provision like a most favored nations clause, or both—and would have been permitted to launch its generic product prior to the expiration of the relevant patent(s), but not immediately. ***But none of these members was able to finalize the agreements, because of AB 824***. In one case involving an AAM member, AB 824 led the plaintiff to withdraw the offer of a most favored nations clause, which it had included in settlements completed prior to AB 824's operative date. In another case, AB 824 led the plaintiff to revoke a settlement offer that fell within § 134002(a) ***and invoke AB 824's scope and penalties as the reason***. And in a third case involving an AAM member that holds some patents, the member decided to pull out of a tentative settlement under which the defendant would have received an exclusive license and been allowed to bring its generic onto the market prior to patent expiration, but not immediately, specifically because of AB 824's penalties and its provision deeming exclusive licenses to be things of value. In each of these cases (and others), AB 824 led an AAM member to lose a settlement opportunity, and in turn directly caused an AAM member to continue litigating a case it otherwise would have settled, at enormous cost in terms of legal fees.

76. Those are textbook economic injuries that are directly traceable to AB 824. Coupled with the Attorney General's concession at oral argument regarding its intent to enforce the law against out-of-state settlements, *see supra*, that is more than enough to satisfy Article III. *See Nat'l Audubon Soc'y, Inc. v. Davis*, 307 F.3d 835, 855-56 (9th Cir. 2002) (trappers had standing to challenge new law that penalized certain trapping activity based on their suffering economic injury as a result of abstaining from conduct "they would otherwise" have engaged in but for the new law); *Bland v. Fessler*, 88 F.3d 729, 737 (9th Cir. 1996) (foregone revenue caused by compliance "under the cloud of the civil statute's penalties" created live controversy).

77. AAM's members' injuries that are directly traceable to AB 824 do not end there. In addition to the economic injuries already suffered, AAM's members stand to be subjected to unconstitutional state action. As the Attorney General's concession at oral argument confirms, California fully intends to enforce AB 824 against settlement agreements completed wholly out of state. This stated "plan" to enforce AB 824 regardless of where a settlement is completed, *see* Ex. B at 23:23, confirms beyond doubt that AAM's members face a genuine, credible, and imminent threat of being subjected to unconstitutional state action. In short, the injuries that AAM seeks to remedy here are "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)).

78. In sum, AAM has standing to bring this suit under 42 U.S.C. § 1983, and an actual "Case or Controversy" exists for purposes of Article III. *See* U.S. Const. art. III, § 2.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
(Declaratory/Injunctive Relief—Commerce Clause—Extraterritoriality)

79. AAM re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

80. In light of the Framers' "special concern both with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres," the Supreme Court has long held that, under the Commerce Clause, no state may "control[] commerce occurring wholly outside [its] boundaries." *Healy*, 491 U.S. at 335-36 (footnote omitted). A state law that has "'the practical effect' of regulating commerce occurring wholly outside [the] State's borders" thus "exceeds the inherent limits of the enacting State's authority," and will be struck down "***whether or not the regulated commerce has effects within the State***." *Id.* at 336 (emphasis added).

81. AB 824 transgresses that limitation by its plain terms. AB 824 extends to commerce (namely, patent settlement agreements) even if they were negotiated, signed, and entered wholly outside the borders of California. AB 824 contains no restrictions that would limit its application to settlement agreements between California entities, and no restrictions that would limit its application to settlement agreements that were negotiated, completed, or entered in California. And, as noted, AB 824 subjects the parties to patent settlements ***and the individual people who merely assist in settling patent cases*** to sweeping penalties. AB 824 therefore "exceeds the inherent limits of [California's] authority" under the Constitution. *Id.*

82. Indeed, AB 824 regulates settlement agreements even if neither settling party ever sells any product into California. Under its plain text, AB 824 would reach an agreement even if the agreement was completed entirely out of state, resolved an out-of-state case, and was between two out-of-state companies, and even if neither party to the settlement sells its products directly into California, but rather sells only to national wholesalers and delivers their products outside of California. So long as a patent-litigation settlement has a "connection with the sale of a pharmaceutical product," Ex. A § 134002(a), AB 824 applies to it.

83. In any event, whether or not AB 824 expressly refers to out-of-state commerce is of no moment. The fact that a state law "is addressed only to" conduct "in [the state] ***is irrelevant*** if the 'practical effect'" is to regulate conduct "in other States." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986) (emphasis added); *cf. Sam Francis Found. v. Christie's, Inc.*, 784 F.3d 1320 (9th Cir. 2015) (en banc) ("easily conclud[ing]" that California statute that regulated terms of sales of artworks outside of California, simply because the seller resided in California, violated the Commerce Clause, despite not mentioning other states).

84. At oral argument before the U.S. Court of Appeals for the Ninth Circuit, counsel for the Attorney General stated unequivocally not only that the Attorney General believes it has the constitutional

authority to enforce AB 824 against settlements negotiated, signed, and entered wholly out of state, but that the State fully intends to do so. *See* Ex. B at 22:10–23:24.

85. AB 824 violates the Commerce Clause as applied to settlement agreements that were not negotiated, completed, or entered in California.

SECOND CAUSE OF ACTION
(Declaratory/Injunctive Relief—Preemption)

86. AAM re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

87. AB 824 undermines both the rights conferred in patent law (*e.g.*, the right to grant exclusive licenses) and the pre-expiry market entry of generic drugs. That is contrary to the text and purpose of federal patent law generally and the Hatch-Waxman Act and BPCIA in particular.

88. AB 824 prohibits factfinders from presuming "[t]hat any patent is enforceable." Ex. A § 134002(b)(2). That directly conflicts with federal law, under which "[a] patent shall be presumed valid." 35 U.S.C. § 282(a).

89. That is not the only conflict between AB 824 and the Patent Act. Federal patent law gives patent holders the right to grant competitors exclusive licenses, *i.e.*, authorizations allowing competitors to enter the market before patent expiry in exchange for payment. *See* 35 U.S.C. § 261 ("Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. ***The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States***." (emphasis added)). And the Supreme Court has long recognized the validity of such grants, *see, e.g.*, *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938). Yet AB 824 treats the grant of an exclusive license as presumptively anticompetitive and unlawful whenever it is part of a settlement agreement resolving a patent-infringement lawsuit that does not permit the generic's competing product to enter the market immediately. *See* Ex. A § 134002(a).

90. That, too, is a direct and stark conflict with federal patent law. In *Actavis*, the Supreme Court made clear that its holding (which permitted reverse-payment patent settlements to be subjected to antitrust scrutiny in limited circumstances) should not be construed as impinging upon any "right" the federal patent laws grant patentees, "whether expressly or by fair implication." 570 U.S. at 151. Indeed, *Actavis* held that the kind of "reverse payments" it addressed could be subject to antitrust attack only after the United States Government assured the Court that such payments were unlike an ordinary "exclusive license," which "is expressly authorized by the Patent Act, in Section 261 of Title 35." Oral Arg. Tr. 3-4, *FTC v. Actavis, Inc.*, No. 12-416 (U.S. Mar. 25, 2013). And yet, under AB 824, settling a patent suit by exercising the long-established right of a patent holder to grant a competitor an exclusive license—*i.e.*, an authorization allowing the competitor to ***enter*** the market before patent expiry in exchange for payment ***from*** the competitor, *see* 35 U.S.C. § 261—is now grounds for potential state law liability unless the settlement allows the generic to enter the market ***immediately***. *See* Ex. A § 134002(a)(1)-(2). That frustrates the rights federal patent law confers and the timely market entry of lower-priced generic medicines.

91. That is no small conflict. The Supreme Court rejected the FTC's argument that all patent settlements that convey a thing of value to the generic manufacturer should be considered presumptively unlawful precisely because the Court concluded that many (if not most) such settlements will be *pro*competitive. After all, the entry of a generic drug onto the market often brings down prices for patients by many orders of magnitude. In other words, the Court rejected a presumption of illegality because the "balance" between antitrust law and patent law must be taken into account in reviewing patent settlements, and presuming illegality could suppress economically useful conduct in contravention of the purposes of antitrust law. Yet AB 824 implements an even-less-solicitous variant of the argument the Supreme Court rejected in *Actavis*. AB 824 is thus irreconcilable with the purposes of the federal law that governs pharmaceuticals.

92. The conflicts with federal law do not end there, as AB 824 also stands as a powerful obstacle to the accomplishment of the basic purposes of federal patent law.

93. Consistent with the "stated objective of the Constitution in granting the power to Congress to legislate in the area of intellectual property," the federal patent laws "offer[] a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974); *see* U.S. Const. art. I, § 8, cl. 8. "The productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens." *Kewanee Oil Co.*, 416 U.S. at 480; *see, e.g.*, *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) ("[T]he primary purpose of our patent laws is … 'to promote the progress of science and useful arts.'" (quoting U.S. Const. art. I, § 8, cl. 8)).

94. The objectives of Hatch-Waxman are similar but distinct. In enacting Hatch-Waxman, Congress "attempted to balance the goal of 'mak[ing] available more low cost generic drugs' with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement." *King Drug Co. v. SmithKline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (quoting H.R. Rep. No. 98–857, pt. 1, at 14-15 (1984)). Hatch-Waxman "facilitates" the development and entry of generics "by allowing an applicant to file" ANDAs, which are far "less onerous and less costly" than NDAs. *Id.* at 395; *see also Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (Congress's aim in Hatch-Waxman was to "'get generic drugs into the hands of patients at reasonable prices—fast.'" (citation omitted)).

95. Congress has also long regulated anticompetitive conduct that results in higher prices for patients. *See, e.g.*, Sherman Act, ch. 646, 26 Stat. 209 (1890) (codified as amended in 15 U.S.C. §§ 1-7). Indeed, "[t]he balance between the interest in motivating innovation and enlightenment by rewarding

invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other, has been a feature of the federal patent laws since their inception." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998).

96. To be sure, the Supreme Court "has recognized that the federal antitrust laws do not preempt state law" in every instance. *California v. ARC Am. Corp.*, 490 U.S. 93, 101-02 (1989). The Supreme Court has thus allowed states to impose penalties on conduct that would be unlawful under federal law, including penalties that go above and beyond what federal law allows. But, crucially, "federal courts have not hesitated to rule that state antitrust law is preempted by federal law when they determine that state law comes into conflict with some ***other*** federal statute," such as federal patent law or the Hatch-Waxman Act. Richard A. Samp, *The Role of State Antitrust Law in the Aftermath of* Actavis, 15 MINN. J. L. SCI. & TECH. 149, 150 (2014) (emphasis added); *see, e.g., Connell Constr. Co., Inc. v. Plumbers & Steamfitters Local Union No. 100*, 421 U.S. 616, 635-36 (1975) (claim arising under state antitrust law preempted by federal labor law even though conduct that gave rise to state claim could proceed under federal antitrust law).

97. That is for a simple reason: Under our constitutional system, any state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" is therefore invalid. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

98. State laws regulating competition are fully subject to this rule. Such laws have long been "held to be preempted by the federal patent law" when, as here, they conflict with the Patent Act and/or "upset the federally struck balance" between, *e.g.*, competition and innovation. *Morseburg v. Balyon*, 621 F.2d 972, 977 (9th Cir. 1980); *see also, e.g., Edgar v. MITE Corp.*, 457 U.S. 624, 634 (1982) (state laws that "upset the careful balance" of a federal scheme are preempted).

99. It is therefore unsurprising that ***even the California Supreme Court*** has recognized that, because "[t]he United States Supreme Court is the final arbiter of questions of patent law and the extent

to which interpretations of antitrust law—whether state or federal—must accommodate patent law's requirements," states "must abide by [its] judgment" on those issues. *In re Cipro Cases I & II*, 348 P.3d 845, 859 (Cal. 2015).

100. And *Actavis* could not be clearer about the contours of that "judgment" here. *Actavis* emphasized that, in reviewing antitrust challenges to patent settlements, courts must "balance" the competing interests of antitrust law and the federal patent laws, including Hatch-Waxman. As the Court explained, "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Actavis*, 570 U.S. at 148; *cf. United States v. Line Material Co.*, 333 U.S. 287, 310 (1948) (requiring courts to make "an adjustment between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by" antitrust law).

101. Consistent with that required "balance," *Actavis* expressly rejected the argument that all settlements that include any transfer of value from the brand company to the generic should be "presumptively unlawful." 570 U.S. at 158-59; *see* Saul P. Morgenstern, Adam M. Pergament, *Commentary: Applying the Rule of Reason in the Post*-Actavis *World*, 2018 COLUM. BUS. L. REV. 45, 69 (2018) ("The *Actavis* holdings … are clear—no *per se* rules, no quick looks, no presumptions."). What is more, the Court held that antitrust review of patent settlements is appropriate only in narrow circumstances—*viz.*, where the settlement contains a "large and unexplained" payment from the patent holder to the patent challenger—and, even then, that antitrust review is appropriate only pursuant to the rule of reason. *Actavis*, 570 U.S. at 158-59. As the Court made clear, "abandonment of the 'rule of reason' in favor of presumptive rules (or a 'quick-look' approach) is appropriate only where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on consumers and markets.'" *Id.* at 159 (citation omitted).

102. Yet, under AB 824, most patent settlements—*i.e.*, all except for pure entry-date agreements (with non-exclusive licenses), and including even those with no "large and unexplained" payment from the patentee—are presumptively unlawful.

103. Under AB 824, only two conditions must be met for a patent settlement between a brand-name manufacturer and a generic manufacturer to be "presumed to have anticompetitive effects and [to] be a violation of" state law: (A) the generic or biosimilar manufacturer "receives anything of value" from the brand-name manufacturer; and (B) the generic or biosimilar manufacturer "agrees to limit or forego research, development, manufacturing, marketing, or sales" of its generic/biosimilar version of the drug "for any period of time." Ex. A § 134002(a)(1). The term "anything of value"—which is defined to "includ[e]," *inter alia*, "a promise that the brand company will not launch an authorized generic version of its brand drug"—is obviously more capacious than the "large and unexplained" payments to which *Actavis* limited its holding.

104. And as recent data from the FTC make clear, the second condition of § 134002(a) will be satisfied in the overwhelming majority of pharmaceutical patent settlements. In 195 (or more than 84%) of the 232 final settlements the FTC reviewed between October 1, 2015 and September 30, 2016 (the last period for which it has released data), the generic manufacturer agreed to the entry of its product at some time in the future. *See* FTC, *Agreements Filed with the FTC under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016* (May 2019), https://bit.ly/2moUyf2.

105. The FTC further found that most settlements also contain acceleration clauses, which allow generics to enter the market ***even earlier than initially agreed*** if certain agreed-upon conditions come to fruition. Yet such clauses appear to provide "value" to generic or biosimilar developers within the meaning of AB 824—and thus to open up generic companies to costly enforcement actions in California court—even though they accelerate competition by definition.

106. Under the broad terms of AB 824, however, even those (and other, similar) types of contract terms that accelerate generic or biosimilar market entry could potentially trigger the statute's draconian presumption of illegality, notwithstanding the fact that such terms are procompetitive on their face. Indeed, ***most*** small and easily explained "transfers of value" from a brand-name drug company to a generic or biosimilar developer will trigger the statute's presumption of illegality—in direct violation of the federal standards set forth in *Actavis*.

107. The inevitable effect of allowing AB 824 to go into effect will be to scuttle dozens of patent settlements that are fully legal under *Actavis*. Hardly any generic drug manufacturer (or their attorneys and signatories, who are individually liable under the statute) will be willing to risk a "penalty" of the greater of "$20,000,000" or "three times the value received" in a patent settlement, *see* Ex. A § 134002(e)(1)(A), especially given that such penalties are not exclusive of other monetary liability under California (or federal) law, *see* Ex. A § 134002(e)(2).

108. The resulting decline in settlements will upset the careful balance between antitrust law and patent law that, according to the Supreme Court in *Actavis*, Congress sought to achieve.

109. The follow-on effects will frustrate Congress' aims even more so. If generic manufacturers know in advance that any acceptable patent litigation settlement is likely to trigger potentially crippling liability under California law, then generic drug and biosimilar manufacturers will be far less likely to invest the time and money necessary to file aBLAs and Paragraph IV ANDAs in the first place; after all, such filings trigger almost certain patent litigation.

110. And, to be clear, ***that has already happened***: As a direct result of AB 824, AAM members have already withdrawn Paragraph IV ANDAs rather than be put to the Hobson's choice of litigating every blocking patent all the way to judgment or settling a case and risking having its employees and agents be subjected to personal-bankruptcy-inducing penalties under AB 824.

111. The short-term consequences (*i.e.*, direct economic harm to AAM's members) are therefore clear. But the long-term consequences will be even worse. If generic and biosimilar manufacturers are forced to litigate an infringement challenge to every patent that blocks their products' entry onto the market, then the lower-priced but equally safe generic and biosimilar medicines on which Americans rely every day would cease to be available prior to patent expiry in many more cases. Such delays of generic drug and biosimilar entry will harm our entire healthcare system—most notably patients, who will be forced to contend with monopoly prices for brand-name prescription drugs for longer periods of time.

112. AB 824 stands as an obstacle to federal law in yet another way. In holding that the balance federal law erects between the patents and antitrust, *Actavis* rejected any form of antitrust review that provide government regulators or other plaintiffs shortcuts from meeting their burden under the rule of reason. Yet, under AB 824, it is ***the settling parties'*** burden to "demonstrate by a preponderance of the evidence that either" (A) "[t]he value received by the nonreference drug filer … is a fair and reasonable compensation solely for other goods or services that [it] has promised to provide" or (B) "[t]he agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement." Ex. A § 134002(a)(3). If the evidence on those issues is in equipoise, then the settling parties lose, and "[e]ach person who [thereby] violated" the statute (or who "assist[ed] in the violation") will be liable for "a civil penalty" of no less than $20 million. Ex. A § 134002(e)(1)(A).

113. AB 824 also is preempted to the extent it applies to settlements involving biologics and biosimilars. Patent settlements pursuant to the BPCIA are off-limits for state regulation.

114. The subject matter of the BPCIA—biosimilar approval and related patent litigation—involves "a scheme of federal regulation so pervasive" that there is no role for state law to play. *Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 196 F.3d 1366, 1372 (Fed. Cir. 1999). Indeed, not only do the

BPCIA's "carefully crafted and detailed" patent-litigation provisions create a comprehensive procedural roadmap and specific consequences for departing from it, they "intentionally" limit injunctive relief to one circumstance and provide no damages remedy *at all*. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1674-75 (2017).

115. Applying AB 824 to a biologic/biosimilar settlement would thus be a nonstarter, as it would second-guess Congress' explicit and considered decisionmaking and upset the BPCIA's carefully balanced approach, and would invade a field fully occupied by federal law.

116. In sum, AB 824 conflicts with federal patent law and poses an obstacle to the accomplishment of the full purposes and objectives of federal law. It is preempted as a result.

THIRD CAUSE OF ACTION
(Declaratory/Injunctive Relief—Excessive Fines Clause)

117. AAM re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

118. The Eighth Amendment prohibits states from imposing "excessive fines." U.S. Const. amend. VIII; *see Timbs v. Indiana*, 139 S. Ct. 682, 687 (2019) (incorporating the Excessive Fines Clause against the states). The Excessive Fines Clause prevents the government from levying disproportionate civil penalties. *United States v. Bajakjian*, 524 U.S. 321, 328-34 (1998).

119. AB 824 plainly imposes penalties that come within the ambit of the Excessive Fines Clause. Under AB 824, "[e]ach person" who merely "assists in the violation of this section shall forfeit and pay to the State of California a civil penalty" of no less than "twenty million dollars ($20,000,000)." Ex. A § 134002(e)(1)(A). The "penalty" imposed must be "sufficient to deter violations of this section." *Id.*; *see Bajakjian*, 524 U.S. at 328-34 (penalties, as opposed to other forms of civil liability, are designed not just to compensate). And only "the Attorney General" and "attorneys designated by it" may sue to collect the "penalty" AB 824 imposes. Ex. A § 134002(e)(1)(B). The penalty goes only to the State, not any private party—just like classic civil penalties. In sum, § 134002(e)(1)(A)'s "penalty" is clearly

intended as a punishment, and it is therefore a "fine" within the meaning of the Eighth Amendment's Excessive Fines Clause.

120. The penalties AB 824 authorizes are grossly excessive. A fine is excessive within the meaning of the Eighth Amendment when it is "grossly disproportional to the gravity of a defendant's offense." *Bajakjian*, 524 U.S. at 334; *see generally United States v. Mackby*, 261 F.3d 821, 829 (9th Cir. 2001). The ***minimum*** penalty for all "person[s]" who merely "***assist[] in [a] violation***" is $20 million, ***even if they "ha[ve] not received any value***." Ex. A § 134002(e)(1)(A) (emphasis added). And there is no de minimis requirement or textual criteria for determining what constitutes "assistance" that triggers the $20-million-or-more penalty. Under the text of the statute, rather, ***all "person[s]"*** who assist in a violation—not just all "parties" deemed to violate the statute—may be punished to the tune of $20 million apiece.

121. Penalties that start at $20 million and go up from there are plainly excessive vis-à-vis any individual—such as junior associate at a law firm representing one of the parties or a secretary to one of the parties' CEOs—who merely assists in settling a lawsuit and derives no value therefrom. Indeed, no one could seriously claim that there are circumstances under which a $20-million penalty would *not* be "grossly disproportionate" vis-à-vis an individual (like an associate at a law firm representing one of the parties or a secretary who works for one of the parties' CEOs) who did not receive anything of value as a result of her assistance.

122. The penalties AB 824 imposes are therefore unconstitutional.

FOURTH CAUSE OF ACTION
(Declaratory/Injunctive Relief—Due Process—Burden-Shifting)

123. AAM re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

124. AB 824 places "the burden of persuasion—the notion that if the evidence is evenly balanced, the party that bears the burden of persuasion must lose"—on the defendant, even in suits brought

by the Attorney General seeking massive monetary penalties. *See Dir., Office of Workers' Comp. Programs, Dep't of Labor v. Greenwich Collieries*, 512 U.S. 267, 272 (1994).

125. Under AB 824, it is the settling parties' burden to "demonstrate by a preponderance of the evidence that either": (A) "[t]he value received by the nonreference drug filer … is a fair and reasonable compensation solely for other goods or services that [it] has promised to provide"; or (B) "[t]he agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement." Ex. A § 134002(a)(3). If the evidence on those issues is in equipoise, the settling parties lose, and "[e]ach person who [thereby] violated" the statute (or who "assist[ed] in the violation") will be liable for "a civil penalty" of no less than $20 million and potentially far more. Ex. A § 134002(e)(1)(A).

126. "[D]ue process forbids" states from "from shifting the burden of persuasion to defendants" in this way. *Back v. U.S. Dep't of Agric.*, 445 F. App'x 826, 829 (6th Cir. 2011).

127. AB 824 also deprives defendants of "'an opportunity to present every available defense.'" *See Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) (quoting *Lindsey v. Normet*, 405 U.S. 56, 66 (1972)). Most patent settlements take years to be completed. As a result, manufacturers usually will not be able to show that a settlement ***already has*** "generated" benefits, *see* Ex. A § 134002(a)(3)(B), even if it undoubtedly ***will*** have such benefits over its lifetime.

128. AB 824 therefore violates the Due Process Clause.

PRAYER FOR RELIEF

WHEREFORE, AAM prays for:

A. a declaration, pursuant to 28 U.S.C. § 2201, that AB 824 violates the United States Constitution and is therefore void and unenforceable;

B. a preliminary injunction prohibiting the Attorney General from implementing and enforcing AB 824;

C. a permanent injunction prohibiting the Attorney General from implementing and enforcing AB 824;

D. such costs and reasonable attorney's fees to which it might be entitled by law; and

E. any other relief the Court deems just and proper.

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